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New Immune Globulin Subcutaneous (Human), 10% (IGSC) Product is Well Tolerated in Subjects with Primary Immunodeficiency Diseases (PID)

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Abstract:

RATIONALE: To evaluate the tolerability of a new IGSC 10% product in PID subjects. **METHODS:** A multi-center, prospective, open-label study evaluated efficacy, tolerability and pharmacokinetics of IGSC, 10% given IV or SC to 49 PID subjects. Tolerability of SC infusions was evaluated by the frequency of adverse events (AEs), rate and volume of SC infusions, and observing the percentage of interrupted, reduced or stopped infusions due to tolerability reasons. **RESULTS:** 47 evaluable PID subjects received a total of 2,294 SC infusions. 4.9% of infusions were associated with local AEs at the start of SC treatment, decreasing to 1.1% at the end of study. No serious AEs were considered related to IGSC 10%. 99.8% of the SC infusions were completed without interruption, rate reductions or discontinuation due to tolerability reasons. The median duration of infusions was 1.2h (range 0.6-3.7h). The median maximum SC infusion rate was 20.0 mL/h/site (range 10.0-30.0 mL/h/site) in subjects 2 to <12 years of age, and 30.0 mL/h/site (range 8.0-40.0 mL/h/site) in subjects ≥ 12 years of age. A low overall temporally associated AE rate (8%), and a low rate of local AEs (2.8%) were seen with infusions volumes of up to 30 mL/site and infusions rates of up to 30 mL/h/site. None of the reported local AEs were severe in nature. **CONCLUSIONS:** This study seems to demonstrate that the IGSC 10% product is well tolerated in PID subjects tested. IGSC 10% infusion times were similar to reports of higher concentration IGSC products, with less reported local AEs rates.

Author Disclosure Information: **W.J. Grossman:** Employee, Baxter BioScience. **R.L. Wasserman:** DallasAllergyImmunology, Physician, CSLBehring, GSK, Consultant, Speaker, Baxter Healthcare, Talecris, Consultant, CSLBehring, Baxter Healthcare, Talecris, Octapharma, Nabi, GSK, Medimmune, TEVA, Principle investigator, George, Hartz & Lundeen, Expert witness, AAAAI, Board of Directors. **I. Melamed:** IMMUNOe, President, Grifols Educational Grant, Baxter Educational Grant, Grant, CSL Behring, Pfizer, Teva, Baxter, Octapharm, GSK, Novartis, MedImmune, Ception, Principle investigator. **M. Stein:** CSL Behring, Speaker, CSL Behring, Baxter Healthcare Corp, Bio Product Laboratory, Biotest Pharmaceuticals Corp., Investigator, Allergy Associates of the Palm Beaches, President. **W. Engl:** Baxter BioScience, Employee. **H. Leibl:** Baxter BioScience, Employee. **R.I. Schiff:** Baxter

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